Request for Approval Under the Generic Clearance for Emergency Epidemic Investigation Data Collections (0920-1011)

Instruction: This form should be completed by the primary contact person from the CDC CIO that will be sponsoring the investigation.

Determine if your investigation is appropriate for this Generic mechanism: *Instruction: Before completing and submitting this form, determine first if the proposed investigation is appropriate for the EEI Generic ICR mechanism. Complete the checklist below. If you select "yes" to all criteria in Column A, the EEI Generic IR mechanism can be used. If you select "yes" to any criterion in Column B, the EEI Generic ICR mechanism cannot be used.*

Column A	**Column B**
CDC epidemiological assistance is requested by one or more external partners (e.g., local, state, tribal, military, port, other federal agency, or international health authority or other partner organization). ☒ Yes ☐ No	The Investigation is initiated by CDC, without request from an external partner. ☐ Yes ☒ No
The investigation is urgent in nature (i.e., timely data are needed to inform rapid public health action to prevent or reduce injury, disease, or death). ☒ Yes ☐ No	The investigation is not urgent in nature. ☐ Yes ☒ No
The investigation is characterized by undetermined agent, undetermined source, undetermined mode of transmission, or undetermined risk factors. ☒ Yes ☐ No	The investigation is conducted for the primary purpose of program evaluation, surveillance, needs assessment, or research to contribute to generalizable knowledge. ☐ Yes ☒ No
One or more CDC staff (including trainees and fellows) will be deployed to the field. ☒ Yes ☐ No	CDC staff (including trainees or fellows) are not deployed to the field. ☐ Yes ☒ No
Data collection will be completed in 90 days or less. ☒ Yes ☐ No	Data collection expected to require greater than 90 days. ☐ Yes ☒ No

Did you select "Yes" to ***all*** criteria in Column A?

If yes, the EEI Generic ICR may be appropriate for your investigation. → You may proceed with this form.

Did you select "Yes" to ***any*** criterion in Column B?

If yes, the EEI Generic ICR is not appropriate for your investigation. → Stop completing this form now.

GenIC # 2016 - 023 **Date** 08/15/2016

Title of Investigation: *Instruction: Provide the title of the investigation in the following format: [Undetermined agent, undetermined source, undetermined mode of transmission, undetermined risk factor] for [disease/problem] among [subpopulation]—[State], [Year]*

Undetermined source for *Salmonella* Infantis infections among detention center inmates — South Carolina, 2016

Location of Investigation: *Instruction: Indicate location where investigation will occur. If multiple locations, specify each one.*

State:	South Carolina
City/County (if applicable)	Lexington
Country	USA

Requesting Agency: *Instruction: Indicate name of agency requesting epidemiological assistance and the name and position title of the requestor*

Agency:	South Carolina Department of Health and Environmental Control
Name and Position Title:	Linda J. Bell, M.D. State Epidemiologist

Note: Attach the Letter of Invitation requesting support. The letter should include the following information: 1) background on the outbreak or event; 2) steps already taken toward prevention and control, if any; 3) request for CDC assistance, including objectives of the investigation; and 4) how data will be used to inform prevention and control measures. Sensitive information in the Letter of Invitation not appropriate for public dissemination should be redacted.

Description of Investigation

1. Problem to be Investigated: *Instruction: Provide a summary of the outbreak or event. The summary should include all the information you know at this time about the outbreak or event and the investigation that is planned. At a minimum, please provide the following information: 1) background necessary to understand the importance of the outbreak or event, including a justification of the need for an investigation and why this issue requires an urgent response; 2) the objectives of the investigation, including how the information collected will be used to inform prevention and control measures; and 3) a brief overview of the investigation planned, including study design, respondents, mode of data collection. In the description, indicate whether a data collection instrument is attached with the GenIC request (refer to as Appendix 1, etc) and what instruments will be developed in the field. (suggested length: 250-500 words).*

On July 27, 2016, the South Carolina Department of Health and Environmental Control notified CDC of a cluster of illnesses with isolates matching a rare, emerging strain of Salmonella Infantis, defined by the PFGE pattern JFXX01.0787. To date, 131 cases of gastrointestinal illness have been identified in this cluster. The source of infection among this cluster of illnesses is currently unknown.

Salmonella Infantis is known to cause long-term, asymptomatic infections. It also causes more severe infections than other common Salmonella serotypes. This Salmonella Infantis strain is of particular public health interest because previous isolates matching this PFGE pattern have been found to contain a large mobile plasmid containing a CTX-M-65 type extended-spectrum beta-lactamase, as well as resistance to 9-10 other drugs. Previous isolates of this strain have demonstrated resistance to ampicillin, ceftriaxone, chloramphenicol, sulfisoxazole, tetracycline, nalidixic acid, trimethoprim/sulfamethoxazole, and intermediate susceptibility to ciprofloxacin and

gentamicin; this strain is associated with more severe illness than other Salmonella Infantis strains.

Phylogenetic analysis conducted on clinical isolates from this cluster revealed close clustering with previously characterized isolates, as well as a CTX-M-65-positive isolate from retail chicken. Due to frequent association of this strain with a clinically important multidrug resistance, the epidemic potential of the MDR plasmid, and the potential association with chicken, an urgent public health response is warranted.

The South Carolina Department of Health and Environmental Control has requested CDC assistance to:
1) Describe the extent of the cluster of gastroenteritis among detention center inmates.
2) Assess exposures and risk factors for acquisition of Salmonella Infantis infection.
3) Describe the clinical course of illness of affected patients including severity of infection, treatment and outcomes.
4) Determine if persons previously reporting illness are currently shedding Salmonella Infantis PFGE pattern, JFXX01.0787.
5) Based on findings of the investigation, recommend measures to reduce inmate risk and for ongoing surveillance.

Data on illness and risk factors will be collected via interviews with detention center inmates (Appendix 1) and medical record abstraction conducted by federal employees (Appendix 2).

2. Characteristics of Outbreak or Event (Check all that Apply):

- ☐ Undetermined agent
- ☒ Undetermined source
- ☐ Undetermined mode of transmission
- ☒ Undetermined risk factor

3. Respondents: *Instruction: Select all that apply. For each respondent type selected, provide a brief description. Be sure to include a description of control respondents, if applicable. Use as much space as necessary for each description.*

- ☐ General public (describe):
- ☐ Healthcare staff (describe):
- ☐ Laboratory staff (describe):
- ☐ Patients (describe):
- ☐ Restaurant staff (describe):
- ☒ Other (describe):

  Cases and controls will be detainees in a county detention facility present during the time of the cluster (Appendix 1).

4. Selection of Respondents: *Instruction: Provide a brief description of how respondents will be identified and selected. Use as much space as necessary for the description.*

Appendix 1: Cases will be identified based on known illness, as recorded by the medical staff at the facility. Controls will be identified from the general population of the detention facility using rosters from the time of the cluster.

Appendix 2: Medical charts will be extracted by federal staff on the Epi-Aid Team.

5. Study Design: *Instruction: Select all that apply. For each study design planned, provide a brief description. Use as much space as necessary for the description.*

☒ Epidemiologic Study (indicate which type(s) below)

- ☐ Descriptive Study (describe):
- ☐ Cross-sectional Study (describe):
- ☒ Cohort Study (describe):
  To describe the cluster (e.g. attack rate), demographics of persons present when the cluster occurred, food exposures, pre-illness medication exposures, medical history and treatment.
- ☒ Case-Control Study (describe):
  To determine food exposures associated with illness, and comorbidities associated with severe illness.
- ☐ Other (describe):

☐ Environmental Assessment (describe):

☐ Laboratory Testing (describe):

☐ Other (describe):

6. Data Collection Mode: *Instruction: Select all that apply. For each data collection mode planned, provide a brief description. Use as much space as necessary for the description.*

☒ Survey Mode (indicate which mode(s) below):

- ☒ Face-to-face Interview (describe):
  The case-control questionnaire (Appendix 1) will be administered via face-to-face interview (for inmates still within the facility) and via telephone interview (with inmates who have been discharged from the facility).
- ☒ Telephone Interview (describe):
  The case-control questionnaire (Appendix 1) will be administered via face-to-face interview (for inmates still within the facility) and via telephone interview (with inmates who have been discharged from the facility).
- ☐ Self-administered Paper-and-Pencil Questionnaire (describe):
- ☐ Self-administered Internet Questionnaire (describe):

☐ Other (describe):

☒ Medical Record Abstraction (describe):
The team of federal staff will review detainee medical records at the detention facility (Appendix 2)

☒ Biological Specimen Sample
Stool samples may be collected to determine if persons previously reporting illness are currently shedding *Salmonella* Infantis PFGE pattern, JFXX01.0787.

☐ Environmental Sample:

☐ Other (describe):

7. Type of Information to be Collected: *Instruction: Select all that apply. For each type of information to be collected, provide a brief description. Use as much space as necessary for the description.*

☒ Behaviors (describe):
Hand washing, food preference

☒ Clinical information/symptoms (describe):
Description of clinical signs and symptoms, symptom onset and duration, treatment

☐ Contact information (describe):

☒ Demographic information (describe):
Age, sex, race, ethnicity

☒ Environmental factors (describe):
Housing unit, date of admission to the detention facility

☒ Exposures (describe):
Food history

☒ Medical history (describe):
Current and recent medications, comorbidities

☒ Risk factors (describe):
Demographic, clinical, food history

☒ Specimen/lab information (describe):
Stool samples from detainees to determine if they are shedding *Salmonella* Infantis PFGE pattern, JFXX01.0787.

☐ Travel history (describe):

☐ Other (describe):

8. Duration of Data Collection (number of weeks):
3

Research Determination: *Instruction: Indicate the research determination decision. If the decision is research, provide the research determination letter and IRB approval, if required.*

☐ Research ☒ Not Research

CDC Investigation Lead: *Instruction: Indicate the name, title, and affiliation of the person who will serve as the CDC lead for this investigation.*

Name:	Sarah Luna, PhD
Title:	EIS Officer
Affiliation:	NCEZID/DFWED/EDEB

CDC Sponsoring Program and Primary Contact Person: *Instruction: Indicate the sponsoring CIO/Division/Branch for this investigation. Indicate the name, title, and contact information of the CDC Primary Contact Person for this investigation. Indicate the preferred method of contact during the OMB approval process. Note, contact person or a designee must be available during the OMB approval process in case questions arise.*

CIO/Division/Branch:	Cheri Grigg, DVM, MPH, DACVPM
Name:	Veterinary Medical Officer
Title:	NCEZID/DFWED/EDEB

Certification: *Please read the certification carefully. Type your name to validate that you are providing certification. Note: If you incorrectly certify, the collection will be returned as improperly submitted or it will be disapproved. Certification should be signed by the CDC Primary Contact Person for this Investigation.*

I, [insert name of CDC sponsoring program contact], certify the following to be true:

1. The collection is voluntary.
2. Respondents will not be personally identified in any published reports of the study.
3. Information gathered will be primarily used to inform effective prevention and control measures.

CDC Sponsoring Program Primary Contact Name:	Cheri Grigg
Date of Certification:	8/15/2016

Requested Approval Date (mm/dd/yyyy): *Instruction: Indicate the date by which approval is needed.*

8/16/2016

E-mail the completed form to the Information Collection Request Liaison (ICRL) or EIS program ICRL designee.

EEI Information Collection Request Liaison:
Danice Eaton, PhD, MPH
EIS Program Staff Epidemiologist
EWB/DSEPD/CDC
2400 Century Center, MS E-92
Office: 404.498.6389
Deaton@cdc.gov

For internal use. Do not complete.

Date/Time initial GenIC received by ICRL	
Date/Time final GenIC received by ICRL	
Date/Time submitted to OMB	
Date/Time approved	
